Recommended Background Readings for Pediatric Oncology Subcommittee Meeting
November 28, 2001

Boos J
Drug Trials in Pediatric Oncology:a multi-faceted problem Int J of Clin Pharm and Therapeutics 36(11):613-620 1998
A perspective and summary of several critical factors

Rowinsky EK
The Pursuit of Optimal Outcomes in Cancer Therapy in a New Age of Rationally Designed Target-Based Anticancer Agents. Drugs 60 (Suppl 1):1-14 2000
Commentary on approaches to drug development

Shah S, Weitman S, Langevin AM, Bernstein M, Furman W, Pratt C
Phase I therapy trials in children with cancer. J Pediatr Hematol Oncol 20(5):431-8,1998
Previous results and expectations with regard to safety and efficacy in pediatric phase I studies

Estlin EJ, Ablett S, Newell DR, Lewis IJ, Lashford L, Pearson ADJ
Phase I trials in pediatric oncology- the European perspective. Invest. New Drugs 14:23-32 1996
General commentary on experience in the United Kingdom Children's Cancer Study Group

Smith M, Bernstein M, Bleyer WA, Borsi JD, Ho P, Lewis IJ, Pearson A, Pein F, Pratt C, Reaman G, Riccardi R, Seibel N, Trueworthy R, Ungerleider R, Vassal G, Vietti T
Conduct of Phase I trials in children with cancer. J Clin Oncol 16(3) 966-78 1998
An international consensus document on the design and implementation of phase I studies

Eisenhauer EA, O'Dwyer PJ, Christian M, Humphrey JS
Phase I clinical trial design in cancer drug development. J Clin Oncol 18(3):684-692 2000
General discussions on phase I trial design

Seymour L and Eisenhauer EA
A review of dose-limiting events in phase I trials:antimetabolites show unpredictable relationships between dose and toxicity. Cancer Chemother Pharmacol 47:2-10 2001
Evidence for the rationale for proceeding with studies

Carlson L, Ho P, Smith M, Resich J, Weitman S
Pediatric Phase I Drug Tolerance: A review of recent adult and pediatric Phase I trials. J Pediatr Hematol Oncol 18(3):250-6 1996
Age and therapy dependent differences in drug tolerance

Somia N and Verma IM
Gene Therapy:Trials and Tribulations Nature Reviews Genetics 1(2):91-99 2000
Commentary on some of the special considerations involved in gene therapy studies

Burke GAA, Estlin EJ, Lowis SP
The role of pharmacokinetic and pharmacodynamic studies in the planning of protocols for the treatment of childhood cancer. Cancer Treatment Reviews 25:13-27 1999
Summary of many of the critical considerations in protocol planning

Leeder JS
Pharmacogenetics and Pharmacogenomics. Pediatr Clinics of North America 48(3):765-781 2001
Review of the changes that occur with age as well as among people

Evans WE and Relling MV
Pharmacogenomics:translating functional genomics into rational therapeutics. Science 286:487-491 1999

Review of the application of genomic knowledge to studies and therapy

Sinnett D, Krajinovic M, Labuda D
Genetic susceptibility to childhood acute lymphoblastic leukemia. Leukemia and Lymphoma 38(5-6):447-462 2000
Specific example of the potential contribution of genomics to understanding childhood malignancy

Weitman S, Ochoa S, Sullivan J, Shuster J, Winick N, Pratt C, Vietti T, Harris M
Pediatric Phase II cancer chemotherapy trials : Pediatric Oncology Group study J Pediatr Hematol Oncol 19(3):187-91 1997
A review of data and perspective on phase II studies

Dent S, Zee B, Dancey J, Hanauske A, Wonders J, Eisenhauer EA
Application of a new multinomial phase II stopping rule using response and early progression. J Clin Oncol 19(3):785-791 2001
Examples of an approach to phase II design and analysis

Smith MA and Anderson B
Phase II window studies: 10 years of experience and counting. J Pediatr Hematol Oncol 23(6):334-337 2001
Summary of phase II window experience with commentary and recommendations

Goodman SN
Toward evidence-based medical statistics 1: The P Value Fallacy Ann Intern Med 130:995-1004 1999

Goodman SN
Toward evidence-based medical statistics. 2: The Bayes Factor. Ann Intern Med 130:1005-1013 1999
Two related perspectives on analyzing results from clinical studies